510(k) Summary K072196

Special 510(k) Premarket Notification: Device Modification
Morpheus® CT PICC and Procedure Kit

AUG 27 2007

Manufacturer and sponsor of the 510(k):

AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury, New York 12804
Establishment registration number: 1319211
Contact: Teri Juckett, Regulatory Affairs Manager
518-798-1215 x 1142 Phone
518-798-3625 fax
Date: 16 August 2007

Device Identification:

Proprietary Name:	AngioDynamics, Inc. Morpheus® CT PICC and Procedure Kit
Common Name:	Peripheral Inserted Central Catheter
Classification Name:	Percutaneous, Implanted, Long-Term, Intravascular Catheter
Classification Number:	21 CFR §880.5970
Classification Panel:	Division of Anesthesia, General Hospital, Infection Control and Dental Devices
Product Code:	LJS
Regulatory Class:	II

Legally marketed device to which equivalence is claimed:

AngioDynamics, Inc. Morpheus PICC and Procedure Kit, 510(k) K041420, K060887, K070613, K070615)

Intended Use / Indications

The AngioDynamics, Inc. Morpheus® CT PICC and Procedure Kit is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injections of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Device Description

The AngioDynamics, Inc. Morpheus® PICC and Procedure Kits are currently available in sizes ranging from 3F – 5F Single Lumen and 5F – 7F Dual Lumen Catheters. The catheter shaft has ink markings spaced 1 cm apart. These markings start at the hub and proceed distally to the catheters' tip. The markings provide the physician a guide to use when trimming the catheter to the desired length. The Morpheus® CT PIC Catheter is to be labeled at the following CT Injection Flow Rates:

Catheter Size	Catheter Length	CT Flow Rate	Avg. Static Burst Pressure (Occluded Catheter)	Avg. Dynamic Burst Pressure (Unoccluded Catheter)
3F Single	65 cm	1 mL/sec	311 psi	742 psi
4F Single	65 cm	4 mL/sec	303 psi	817 psi
5F Single	65 cm	7 mL/sec	260 psi	*
5F Dual	65 cm	5 mL/sec	217 psi	611 psi
6F Dual	65 cm	7 mL/sec	262 psi	620 psi
7D Dual	65 cm	8 mL/sec	260 psi	*

*Dynamic Burst testing was conducted using an extremely high flow with the distal end open; no burst resulted for these sizes.

Substantial Equivalence:

The AngioDynamics, Inc. Morpheus® CT PICC and Procedure Kit has similar indications for use, principles of operation, technological characteristics, and performance testing results as compared to the predicate device supporting a determination of substantial equivalence.

Test Data:

The AngioDynamics, Inc. Morpheus® CT PICC and Procedure Kit was subjected to the following tests to assure reliable design and performance under the specified testing parameters:

Catheter Burst (Positive Pressure) Static

Catheter Burst (Positive Pressure) Dynamic

Labeled CT Flow Rate

CT Injection

Tip Whip

Tip Displacement

Summary of the clinical performance data

No clinical tests were performed to determine substantial equivalence.

Conclusions drawn from the non-clinical performance data

The non-clinical tests demonstrate that the device is equivalent to the performance of currently available Morpheus® CT PICC and Procedure Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 7 2007

Ms. Teri Juckett
Regulatory Affairs Manager
AngioDynamics, Incorporated
603 Queensbury Avenue
Queensbury, New York 12804

Re: K072196
Trade/Device Name: AngioDynamics, Inc. Morpheus® PICC and Procedure Kit
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 6, 2007
Received: August 7, 2007

Dear Ms. Juckett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Application: Special 510K Device Modification

Device Name: AngioDynamics, Inc. Morpheus® PICC and Procedure Kit

Indications for Use:

The AngioDynamics, Inc. Morpheus® CT PICC and Procedure Kit is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injections of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Prescription Use X **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

Please do not write below this line - continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices